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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,642	09/29/2004	Yasuyuki Shirota	1017-005	4290

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EXAMINER	
MCCORMICK EWOLDT, SUSAN BETH	
ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 05/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/509,642	SHIROTA, YASUYUKI	
	Examiner	Art Unit	
	S. B. McCormick-Ewoldt	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of species, *Malus domestica*, in the reply filed on March 9, 2006, is acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicants" cancellation of claim 1-9 in the reply filed March 9, 2006 is also acknowledged.

Claims 14-16 and 20-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claims 10-13, 17-19 and 23-29 have been examined on the merits solely in regard to the elected species.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 10-13, 17-19, and 23-29 are rejected under USC 101 because the claimed invention is directed to non-statutory subject matter.

The instant claims read upon products of nature for the following reasons. As drafted, the claims read upon an apple, including an apple still attached to a tree - i.e., at some point during the natural stages of fruit maturation (from unripe/immature fruit to ripe/mature fruit), the polyphenolic substances within an apple (*Malus domestica*) - such as a semi-ripe (semi-mature) apple - would inevitably and necessary be within levels that correlate to those within a mixture of immature apple and mature apples (as claimed/disclosed), given that the levels of such polyphenolic substances (inherently the same substances in both the immature and mature fruit) apparently start off high and gradually decrease during the maturation process. Since polyphenolic substances are natural compounds found within such fruit (including within semi-ripe/semi-mature fruit - i.e., not just in a combination of immature and mature fruit: also see art rejections below), the instantly claimed invention reads upon such products of nature.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-13, 17-19, and 23-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunopotentiator (anti-cancer) drug comprising polyphenols derived from mature and immature fruit obtained from *Malus domestica* (aka - apples; as well as fruit from the non-elected species *Malus pumila* - aka crabapple), does not reasonably provide enablement for providing a composition having an immunopotentiator effect comprising any and all substances derived from any and all fruit from the entire plant kingdom. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

With respect to the elected invention, Applicants have reasonably demonstrated/disclosed that a composition comprising polyphenols from a combination of mature and immature *Malus domestica* fruits provide immunopotentiating (anti-cancer) activity. However, the claims encompass an immunopotentiator drug obtained from undefined substances obtained from undefined mature and immature fruit from among all those found within the entire plant kingdom which read upon millions and millions of potential fruits and fruit combinations, which is clearly beyond the scope of the instantly claimed/disclosed invention.

Accordingly, based upon vast plethora of potential fruits and fruit combinations encompassed by the instant claim language, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to provide a composition comprising substances obtained from mature and immature fruit having the instantly claimed/disclosed function immunopotentiating (anti-cancer) effect, other than a composition comprising effective amounts of polyphenols derived fruit obtained from mature and immature *Malus domestica* fruits.

It is strongly suggested that Applicants limit the claims accordingly so as to overcome the above rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-13, 17-19 and 23-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 10, 24-27, the metes and bounds of the term "raw" are not clearly delineated - i.e., this term is unclear because it is not apparent as to what is encompassed by this term.

In claims 10, 24-27, the metes and bounds of the term "raw" are not clearly delineated - i.e., this term is indefinite because it is not defined in the specification.

In claims 10, 24-27, the metes and bounds of the term "substance" are not clearly delineated - i.e., this term is indefinite because it is not defined in the specification.

In claims 10, 24-27, the metes and bounds of the term "mature" are not clearly delineated - i.e., this term is indefinite because it is not defined in the specification.

In claims 10, 24-27, the metes and bounds of the term "immature" are not clearly delineated - i.e., this term is indefinite because it is not defined in the specification.

Claim 12 recites the limitation "the species" in line 1. There is insufficient antecedent basis for this limitation in the claim.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-13, 17-19, and 23-29 are rejected under 35 U.S.C. 102(b) as anticipated by an semi-ripe (semi-mature) apple (*Malus domestica*) found in nature prior to the instant filing date.

For the reasons set forth under USC 101, the claims, as drafted read upon a semi-ripe (semi-mature) apple found in nature prior to the instant filing date. That is, at some point during the natural stages of fruit maturation (from unripe/immature fruit to ripe/mature fruit), the polyphenolic substances within an apple (*Malus domestica*) - such as a semi-ripe (semi-mature) apple - would inherently be within levels that correlate to those within a mixture of immature apple and a mature apple immature apples (as claimed/disclosed), given that the levels of such polyphenolic substances (inherently the same substances in both the immature and mature fruit) start off high and gradually decrease during the maturation process (as instantly disclosed). Since polyphenolic substances are natural compounds found within such fruit (including within semi-ripe/semi-mature fruit - i.e., not just in a combination of immature and mature fruit), the instantly claimed invention reads upon such products of nature - reads upon natural semi-ripe (semi-mature) apples (and juice thereof) at the point in which the polyphenolic substances therein would inevitably be within levels that correlate to those instantly claimed/disclosed.

Accordingly, as drafted, the instantly claimed invention is anticipated by semi-ripe (semi-mature) apples (obtained from the tree *Malus domestica*) found in nature prior to the instant filing date.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10-13, 17-19, and 23-29 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kanda *et al.* (Biosci. Biotech. Biochem., 1998), as well as over the prior art. with respect to commercial apple juice preparations.

A composition (and/or food) comprising substances derived from immature and mature *Malus domestica* fruit (aka apple) is claimed.

Kanda *et al.* teach compositions comprising polyphenols obtained from immature apples (in amounts which were three to ten times higher than that of mature fruits - see entire document including, e.g., page 1284, first column, 2nd paragraph). Please note that the compositions taught by Kanda *et al.* also read upon a food since nothing would preclude ingestion thereof.

One or more of the reference apple polyphenol compositions would appear to anticipate the presently claimed composition for the following reason. A mature apple would also be composed of the same polyphenols as those found in an immature apple (albeit, in lower amounts than found in immature apples). Accordingly, one or more of the apple polyphenol compositions (comprising variable amount ranges of naturally-occurring apple polyphenols therein) would, thus, read upon a composition comprising polyphenols from both sources (mature and immature fruit) since the polyphenols found in the mature fruit are already present in the immature fruit making such a composition indistinguishable from one obtained from a mixture of immature and mature apples. Please note that the claimed intended functional effect (immunopoteniator drug) would be inherent to the apple polyphenol compositions taught by Kanda *et al.* Consequently, the claimed composition appears to be anticipated by the reference.

In the alternative, even if the claimed composition is not identical to the referenced compositions with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced composition(s) is/are likely to inherently possess the same characteristics of the claimed composition particularly in view similar characteristics which they have been shown to share including, e.g., the significant variability with respect to the amounts of polyphenols found within such immature apples. Thus, the claimed composition would have been obvious to those of ordinary skill in the art within the meaning of USC 103.

In addition, commercial apple juices prior to the filing date of the instant application are deemed to anticipate or at least render obvious the instantly claimed composition since the natural polyphenols present therein would appear to anticipate and/or be obvious within the meaning of USC 103 over the instantly claimed composition comprising substances (polyphenols) obtained from the elected mature and immature apples (*Malus domestica*), especially since such apple juice preparations would also assuredly vary widely with respect to the amounts and/or ratios of naturally-occurring polyphenols therein.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, as well as by the prior art with respect to commercial apple juice preparations, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10-13, 17-19 and 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over BBC NEWS "Apple Juice 'protects the heart' "(2001) in view of Tanabe *et al.* (US 5,994,413).

BBC NEWS (2001) beneficially discloses that compounds in apples (i.e. *Malus domestica*) and apple juice called phytonutrients, act in much the same as the red wine or tea do to delay the break down LDL or bad cholesterol. The study showed potential benefits of active compounds in apple juice and apples. In addition, eating apples (i.e. oral administration) also showed potential health benefits as well as positive results from drinking apple juice (whole document).

BBC NEWS (2001) does not disclose wherein immature fruit is specifically used or wherein an aqueous extract is used.

Tanabe *et al.* (US 5,994,413) beneficially disclose that unripe fruit (i.e. immature) contains a large amount of polyphenol compounds, which are obtained by extraction of unripe fruit (column 1, lines 25-26; column 2, lines 15-19). Tanabe discloses that an organic solvent is used to extract the polyphenols from unripe apples (column 4, lines 1-39; Examples 2 -3). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare compositions comprising polyphenols from apples in general (including ripe/mature apples) as well as from immature (unripe) apples based upon the beneficial teachings provided by the cited references, as discussed above. One of ordinary skill in the art would have been motivated to use mature and immature fruit, specifically apples, because of the beneficial properties that both contain, for example, polyphenols. It was clear from BBC NEWS (2001) that compounds in apples (i.e. *Malus domestica*) and apple juice called phytonutrients, act in much the same as the red wine or tea do to delay the break down LDL or bad cholesterol. The study showed potential benefits of active compounds in apple juice and apples. In addition, eating apples (i.e. oral administration) also showed potential health benefits as well as the positive results from drinking apple juice. It was further clear from Tanabe that unripe fruit (i.e. immature) contains a large amount of polyphenol compounds, which are obtained by extraction, using an organic solvent, of unripe fruit. The adjustment of particular conventional working conditions (e.g., using conventional water extraction) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.. Therefore, one of ordinary skill in the art would have had a reasonable expectation to use extracts of mature and immature apples in a composition because of the healthy beneficial properties that they contain.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Summary

No claim is allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiners' supervisor, Terry McKelvey, can be reached at (571) 272-0775. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sbme

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